DEPARTMENT OF THE ARMY
HEADQUARTERS, WALTER REED ARMY MEDICAL CENTER
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Medical Services

TRANSFUSION OF BLOOD AND BLOOD COMPONENTS

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*This regulation supersedes WRAMC Reg. 40-24, dated 2 August 1999.

WRAMC Reg 40-24

1. Purpose. To prescribe policies and procedures concerning the requesting, testing, storage, issuing, transfusion, documentation and accounting of blood and blood products at Walter Reed Army Medical Center (WRAMC).

2. Applicability. This regulation applies to all activities at WRAMC which request, test, store, issue, administer, document and/or account for blood and blood products.

3. References.

a. Army Regulation 40-2, Army Medical Treatment Facilities, General Administration,

b. Army Regulation 40-66, Medical Record Administration,

c. Army Regulation 40-3, Chapter 5, Army Blood Programs,

d. B. Smith, Sandra F. and Duell, Donna J. Clinical Nursing Skills: Basic to Advanced Skills, 4th Ed. 1996.

e. Circular of Information for the Use of Human Blood and Blood Components; American Association of Blood Banks, America's Blood Centers, American Red Cross.

f. Standards for Blood Banks and Transfusion Services, American Association of Blood Banks, 2002.

g. Technical Manual, American Association of Blood Banks (Army Technical Manual 8-227-3),1999.

4. Responsibilities.

a. Chief, Department of Pathology and Area Laboratory Services (DPALS) is responsible for the establishment and operation of the Blood Bank within the Clinical Pathology Service of the Department of Pathology, capable of meeting all of the transfusion medicine requirements of the clinical staff.

b. Chief, Clinical Pathology Service oversees the daily operation of the Blood Bank.

c. Chief, Blood Services is responsible for the overall administrative, resource, technical and total quality management of Blood Services.

d. Medical Director, Blood Services is responsible for the technical, medical and supportive services of the Blood Bank and assures compliance with all standards and

applicable regulatory requirements. The Medical Director is also responsible for providing or obtaining adequate consultation for special problems, for approving all special services and deviations from standard practices.

e. Clinical department/service chiefs are responsible for the appropriate and proper utilization of blood and blood components within their department/service.

5. Policies.

a. General.

(1) Administration. The WRAMC Blood Services consists of three sections (Transfusion, Immunohematology, Donor Center) within the Clinical Pathology Service of the Department of Pathology and Area Laboratory Services. The technical, medical and administrative procedures and policies governing the operations of the Blood Bank are established by the Food and Drug Administration (FDA), Joint Commission on Accreditation of Healthcare Organizations (JCAHO), College of American Pathologists (CAP), American Association of Blood Banks (AABB), and the regulations of the Department of Defense, Department of the Army and the U. S. Army Medical Command. This regulation represents the statement of those policies and procedures as approved by the WRAMC Blood Usage Committee.

(2) The WRAMC Blood Bank is an accredited institutional member of the AABB, and is registered and licensed by FDA.

(3) Blood transfusion is not without risk. Therefore, the prescribing physician must be certain that clinical indications outweigh the risks. The prescribing physician must document the indications for hemotherapy in the patient's medical record. Federal law prohibits the issue of blood and blood products without a physician's prescription.

(4) The ability to prescribe and order blood products is accorded to physicians by the WRAMC Commander, as a derivative of the delineation of privileges. The Commander may revoke or restrict the transfusion privileges of any physician whose use of blood and blood products jeopardizes patient care or violates FDA regulations or AABB, CAP or JCAHO standards. Such revocation represents a restriction of privileges.

(5) Some products and services available in the Blood Bank require consultation with, and approval by, the Blood Bank Pathologist-on-Call. The Medical Director of the Blood Bank, a pathology resident, or a staff pathologist will be available at all times for such consultation, concerning the diagnosis and treatment of hematologic

disorders.

(6) The WRAMC Emergency Preparedness Plan will be followed in mass casualty situations. Transfusions of blood may be limited by availability. Pre-transfusion testing requirements may have to be altered to meet the immediate needs of patient care in such a multicasualty situation.

(7) The Circular of Information for the Use of Human Blood and Blood Components, prepared jointly by the AABB, the American Red Cross and America's Blood Centers, lists the description, indications and use of blood products, as described on all product labels. The Circular should be consulted for the product description, clinical indications, contra-indications, side effects, hazards, and dosage and administration information. This publication has been widely distributed throughout WRAMC and is readily available from the Blood Bank.

(8) Walter Reed Army Medical Center Regulation 40-24 is required reading for all health care providers who are involved with ordering, distribution and administration of blood and blood products. This includes credentialed providers, those in graduate medical education (residents), medical education (medical students) and Department of Nursing personnel. Each department, service or nursing unit involved with ordering, distribution and administration of blood and/or blood products will ensure that annual training is conducted on their safe administration. Each department will maintain documentation that the above two activities have been accomplished.

b. Availability of blood products.

(1) Routine. The following items are routinely available, and may be ordered by authorized physicians without prior consultation, as long as the transfusion meets certain criteria. Requests not meeting criteria require consultation.

(a) Packed Red Blood Cells.

(b) Win Rho (an Rh [D] immune globulin solution, suitable for Intravenous (IV) administration) for antenatal and postpartum administration to Rh (D) negative women and Rh (D) negative patients receiving Rh (D) positive platelets.

(c) Platelet concentrates, random or apheresis.

(d) Fresh Frozen Plasma.

(e) Cryoprecipitate.

(f) Irradiated blood products.

(2) Controlled Availability. Requests for procurement and issue of the above products require approval if the amount requested exceeds certain criteria. Consultation is available between the patient's physician and the pathologist covering the Blood Bank, to assure effective and appropriate therapy.

(3) Restricted. Requests for procurement and issue of the following products will not be approved, unless the patient's physician contacts the pathologist covering the Blood Bank to obtain approval:

(a) Deglycerolized (thawed frozen) red blood cells.

(b) Washed blood products (red cells or platelets).

(c) Cytomegalovirus (CMV) negative blood products.

(d) Approval to crossmatch units of blood in excess of that specified by the Maximum Surgical Blood Ordering Schedule (MSBOS).

(4) Leukocyte Reduced Blood Products. Leukocyte-reduced red blood cells and platelets are available on a limited basis for patients to reduce febrile reactions and the risk of CMV. Many products are filtered at bedside, but pre-filtration during collection is increasing and will affect future availability of these products.

c. Availability of Special Services:

(1) Autologous blood collection. Patients may pre-deposit their own blood prior to surgery by appointment in the Donor Center, a minimum of 5 working days prior to surgery. It is the attending physician's responsibility to assist the patient in making an informed decision by providing all the comparative benefits and risks associated with transfusion of either autologous or homologous blood products. If the patient still elects autologous donation, the patient's physician must complete a request that includes the type of surgery, date of surgery and number and type of blood products to be collected and prepared. Whole blood, packed red blood cells and fresh frozen plasma may be requested to be available for surgery, time permitting. Whole blood and packed red blood cells expire 35 days from the date of collection. The physician must notify the Blood Bank of any change in surgery date, so that products may be frozen to extend their storage life, if necessary. Autologous blood not utilized by the patient will be destroyed and is not made available for other patients. Autologous donors must meet eligibility criteria as required by US Army and blood banking principles for protection of

donor-recipient. There is no age limit, but the donor should weigh no less than 75 lbs and must be able to cooperate with the procedure. A minor must have the consent of a parent or guardian. When a patient is unable to travel to WRAMC for donation, he may donate at another licensed military or civilian facility.

(2) Directed Donations. Blood products will not be collected for transfusion to specific patients. An exception may be granted through consultation with the pathologist covering the Blood Bank, only in the instance of parents donating, by appointment, for their children who do not meet criteria for autologous donation. The parent-donors must meet all allogeneic donor requirements. Like autologous blood, directed donations are not "crossed-over" to other patients. Exceptions for directed donation might also be made for medical reasons, in the uncommon case of a patient that needs a particular donor phenotype, which is not obtainable otherwise.

(3) Therapeutic Phlebotomy. Patients who are generally healthy and can tolerate phlebotomy easily may be phlebotomized by the staff of the Donor Center, by appointment. Requests must be accompanied by a consultation with the pathologist covering the Blood Bank and a prescription, which covers the number and frequency of procedures requested, along with therapeutic goals and restrictions.

(4) Therapeutic Cytapheresis or Exchange Transfusions. These procedures are available at all times, through consultation with the pathologist covering the Blood Bank.

6. Procedures.

a. Specimen Collection. Proper phlebotomy techniques will decrease the risk of hemolyzed samples that most often occur as the result of physical stress on the red cells during collection. Hemolyzed samples cannot be adequately evaluated for the presence of antibody-induced hemolysis during antibody screening or compatibility testing. If a small gauge needle/butterfly must be used with a syringe, avoid pressure at the site and transfer the blood to the vacutainer tube directly (remove the stopper, but do not force the blood flow). Deliver both Standard Form (SF) 518-*Blood or Blood Component Transfusion* and blood sample directly to the Blood Bank, immediately following collection.

(1) Equipment and Supplies. An anti-coagulated specimen is preferred (3-5 mL purple top). Serum separator and “bullet” tubes are not acceptable. Utilize the following: completed SF 518 (see Appendix B), tube label with patient identification, tourniquet, skin antiseptic (iodine or alcohol), appropriate blood collection apparatus (needles - as large as possible), tube label with patient identification, tourniquet, skin antiseptic (iodine syringe/vacutainer, butterfly, etc.).

(2) Samples. The tube label must contain the patient's family member prefix (FMP) and the sponsor's complete social security number, as well as the patient's first and last names. Both the identity of the phlebotomist and date of sample collection must appear on the tube label. A sample's suitability for processing expires 3 days after collection.

(3) Requisition. All requests for blood and blood products must be submitted on an SF 518- *Blood or Blood Component Transfusion* (see Appendix B) and be accompanied by a properly drawn blood sample. The SF 518 must contain the patient's FMP and sponsor's complete social security number, as well as the patient's first and last names. Section I of the SF 518 must be completed and signed by the individual drawing the sample, verifying the sample is from the identified patient and the match between sample and tube. If the patient is to undergo a surgical procedure, the block in Section I entitled "Diagnosis or Operative Procedure" must indicate the type of procedure to be performed, rather than the clinical diagnosis.

(4) Patient/Sample Verification. Avoidance of clerical errors during sample collection will prevent most acute and fatal transfusion reactions. The patient's identification must be positively established at the time the specimen is drawn. Use the patient's wristband to complete the *Patient Identification* section of at least one SF 518; place the identical information on the blood sample tube label. The completed label must be placed on the tube by the phlebotomist, before departing the patient's location. The phlebotomist signs (include signature, date and time) SF 518 section I, *Signature of Verifier* immediately after collecting the blood specimen, to verify that patient identifying information on the SF 518, the tube label, and the patient's identification (wristband or outpatient card) are identical. Blood will not be drawn from a patient who does not have on an identification wristband, with the exception of the Pre-Admission Unit (PAU), which will use the patient’s identification (ID) card. Check for a "same last name alert" if appropriate.

(5) Acceptability. If any portion of the required information described in paragraphs 6.a.(2), 6.a.(3) or 6.a.(4) above is missing or illegible, on either the blood sample tube or the SF 518, or if the information on the blood sample tube does not completely match that of the SF 518, a new blood sample tube (and new SF 518) may be required by the Blood Bank. Improperly collected or identified blood samples will be retained by the Blood Bank staff. When unsuitable blood samples are received, the appropriate hospital staff will be notified immediately. A test report is also generated in CHCS, indicating the receipt of the blood sample and the reason for unsuitability.

b. Operating Room and Pre-operative Requests. Requests for scheduled surgical cases must be received in the Blood Bank sufficiently in advance of surgery to allow for

testing. Specimens and requests received just prior to procedures will be processed but if a problem arises, the requested blood may not be available when requested.

c. Pre-Admission Unit (PAU). A blood type and antibody screen may be requested for a patient who is scheduled to undergo a surgical procedure. Patient samples are often submitted several weeks prior to the scheduled date of surgery. If accompanied by a completed SF 518, a sample is blood-typed and antibody-screened by the Immunohematology laboratory, but that sample is not held for potential crossmatching for surgery. Patient blood samples (and SF 518) may be resubmitted within 72 hours prior to surgery, to ensure their availability for compatibility testing. Submit a fresh sample and SF 518 if the last one drawn is more than 72 hours old. If a sample is not available, and blood transfusion does become necessary during surgery, blood will be provided on an emergency basis. The Blood Bank will not issue type-specific blood to the patient on the basis of results from a previous type and screen; a fresh patient blood sample must be provided, and blood is issued based upon testing of the new sample, in accordance with standard procedures.

d. Special Orders for Blood/Blood Products. The Blood Bank should also be notified in advance when requesting all blood intended for patients with known immunohematologic problems requiring rare, unusual, human leukocyte antigen (HLA) matched, cytomegalovirus (CMV) negative, or phenotypically matched/ sickledex-negative products.

e. Maximum Surgical Blood Ordering Schedule - MSBOS (See Appendix A).

(1) Units of blood will not be crossmatched for a patient unless there is likelihood that the units will be transfused. Unnecessary crossmatching jeopardizes total patient care by making units unavailable for those who actually need the blood and by increasing the outdating and wasting of a precious resource. The MSBOS indicates the total number of units of red cells that will be crossmatched for a variety of common surgical and medical procedures based on historical use. The details of the MSBOS listing are attached as Appendix A.

(2) When a crossmatch request is received for a procedure that is included on the MSBOS, only the number of units indicated by the MSBOS will be crossmatched, regardless of the size of the submitted order. If medical indications are present which may require the provision of more units than indicated by the MSBOS, additional information should be provided and it may be necessary for the patient's physician to contact the pathologist covering the Blood Bank for approval to crossmatch additional units.

(3) Procedures are described below:

(a) Crossmatch (TC). Crossmatch includes determination of the patient's ABO group and Rh (D) type, a screen for unexpected antibodies to red blood cell antigens and the testing for compatibility of the patient's blood with specific red cell units set aside for use by the patient. These units of blood are immediately available after completion of compatibility testing. The patient's sample is held for additional crossmatch, if the need arises.

(b) Type and Screen (TS). Type and Screen includes determination of the patient's ABO group and Rh (D) type and a screen for unexpected antibodies to red blood cell antigens. No units of blood are specifically selected for the patient if the screen is negative. If the screen is positive, a crossmatch is performed and units are set aside for that patient's use. The patient sample is held for crossmatching if needed. Units of blood will be available in approximately 15 minutes if the TS is negative.

(c) When the MSBOS indicates *not applicable* (NA) in the blood order column, experience has shown that transfusion is highly unlikely. In this case, patient samples need not be submitted to the Transfusion Service unless there is clinical suspicion of an unexpected need or an unexpected antibody. In these situations, consultation with the pathologist and documentation on the SF 518 is recommended.

(4) When a patient is found to have a clinically significant red cell antibody, additional units will automatically be procured by the Blood Bank as backup protection, and the patient's physician and/or ward will be notified via the Composite Healthcare System (CHCS). The Blood Bank should attempt to contact the ward or physician by phone. In this case, a TS is automatically converted to a TC. It may be necessary to postpone surgical procedures if compatible blood is not immediately available.

(5) Upon completion of testing, the results of the tests and the availability of red cell products will be entered into CHCS. The laboratory test panel is called Crossmatched Blood Status (CBS) and will indicate the patient's ABO group and Rh (D) type, the presence or absence of unexpected red cell antibodies, the number of units of blood initially crossmatched and the expiration date of the patient sample. It is recommended that results in CHCS be reviewed prior to the patient's arrival for surgery.

7. Informed Consent.

a. Use of WRAMC Overprint 552 (Request for Administration of Anesthesia and for Performance of Operations and Other Procedures) is recommended to document informed consent for blood transfusions (see Appendix D). This overprint is also available on the Clinical Information System (CIS).

b. Treating physicians should obtain informed consent for blood transfusions for patients considering elective surgery, when the need for blood or blood products is anticipated. The most important element of informed consent is communication between the physician and the patient. The referenced *Circular of Information for the Use of Blood and Blood Components* is available from the Blood Bank and provides general information for the physician concerning blood products and their appropriate use.

c. Prior to the patient signing the consent, the physician should give the patient a copy of the current blood transfusion information letter describing the risks, benefits and alternatives associated with blood transfusion. This information letter is printed on the reverse of the SF 522 (Appendix D), and can assist the physician with educating the patient about the associated risks, benefits and alternatives to blood transfusion. Physicians should keep in mind that the informed consent is merely documentation. When counseling a patient for blood transfusion, it is important that the counselor is able to answer questions, provide a contemporaneous explanation of risks and benefits as found in the blood transfusion information letter, as well as alternatives to allogeneic transfusion such as autologous transfusion, or foregoing transfusion. A note documenting this counseling is recommended.

d. A single, properly completed informed consent document in the inpatient record is sufficient for each hospitalization, and may include one or more transfusions of blood or blood products (the total number of transfusions need not be specified). For chemotherapy and other long-term chronically ill patients, a single informed consent document in the outpatient record is sufficient for the entire course of outpatient therapy.

e. As a general rule, obtain informed consent from patients undergoing elective surgeries considered TS procedures according to the MSBOS, to address instances of unanticipated blood transfusions.

f. For patients who predeposit their own (autologous) blood in anticipation of pending surgery, physicians must still obtain informed consent since there are also risks to receiving autologous blood. This will cover those situations when allogeneic (banked) blood may be transfused to patients.

g. In emergent situations in which the patient (or surrogate decision-maker for minor or incompetent patient) is unable to sign the informed consent form and blood is needed to save life, organ or limb, a note in the medical record stating how many units were transfused under these conditions will suffice. Do not attempt to have the patient complete an informed consent retrospectively.

8. Emergency Issue of Blood.

a. In some medical emergencies, a patient's well-being may be jeopardized by deferring transfusion until all routinely required tests have been completed. When such circumstances arise, the patient's physician may authorize the Blood Bank Transfusion Service to issue the blood products prior to completion of the ABO/Rh (D), antibody screen, crossmatch or transfusion transmissible disease testing.

b. If blood is issued prior to completion of any required tests, the patient's physician must indicate in the medical record that the clinical situation was sufficiently urgent to require release of blood before completion of required tests. The Blood Bank will prepare a release form, which must be signed by the physician prior to the release of blood. If unable to sign prior to issue of the blood, the physician may designate a "representative" who will sign the form when picking up the units. The requesting physician will then proceed within five (5) days to the Blood Bank, to sign the release form.

c. Failure to sign the physician's authorization is a violation of licensing and accrediting agency requirements concerning individuals responsible for legal aspects of transfusion. If the requesting physician does not sign the emergency authorization form within five (5) days, the respective service chief will be notified. Delinquencies exceeding thirty (30) days will be referred to the Blood Usage Committee.

9. Routine Issue of Blood.

a. Walter Reed Army Medical Center (WRAMC) Form 1321 (Blood Product Issue and Utilization Review), see Appendix C. Blood will be issued to physicians or hospital staff personnel upon their presentation of a properly completed WRAMC Form 1321. Blood products will not be issued to family members except for previously established programs. The form must contain the patient's full name, family member prefix, full social security number, blood product(s) wanted, date, location, and the name of the physician requesting the blood and current laboratory results. The physician must indicate additional information justifying the need for the specific blood product requested if screening criteria are not met. Products will not be issued unless the patient identification information is complete and corresponds in full to that on Standard Form 518s attached to the units. Requests for other products will be indicated in the applicable section.

b. Maximum Number of Units Issued. Except for emergency situations, only one unit of blood will be issued to the wards at a time. Two units may be issued to patients in the intensive care units, recovery room, operating room, emergency room or dialysis,

who have more than one intravenous line available. Blood for only one patient may be picked up ***by one person*** at a time, without exception. Several units (2-4) of red cells may be packed on ice and issued to an operating room for a procedure that has a high potential for exsanguination (i.e., re-do coronary bypass graft or ruptured abdominal aortic aneurysm repair) and when the physician anticipates an immediate need for them at the commencement of surgery. Blood so prepositioned must be approved by the pathologist covering the Blood Bank and this blood may only be given to the patient for whom it is issued. Any unused blood must be returned to the Blood Bank at the conclusion of the case and may not accompany the patient to the Recovery Room.

c. Autologous blood will not be available for ***5 working days*** following the collection. The Blood Bank will make all efforts to make these products available before this time but there is no way to guarantee that these products can be available for issue. If needed, the blood may be released with a waiver form.

d. The name of the hospital staff member, along with his/her last four social security number (SSN) digits is required for computer entry, when blood products are picked up. This is a mandatory permanent record and necessary portion of the issue procedure. No blood products will be released by the Blood Transfusion Service without recipient identification. No blood product will be transferred from the destination where it was originally sent without notifying the Blood Bank unless the infusion is in progress (i.e., Operating Room to Recovery Room or Intensive Care Unit).

10. Storage of Blood and Blood Products.

a. All blood products must be stored in accordance with Food and Drug Administration regulations, AABB Standards and the conditions stated on each product label.

b. Blood and blood products will not be stored on the wards, or outside the Blood Bank except as indicated in paragraph 9b above. The Blood Bank will ensure compliance with FDA and AABB requirements.

c. All unused, contaminated or otherwise unsuitable blood products *that were not transfused at all* must be returned to the Blood Bank for destruction. Otherwise, the Blood Bank will assume they have been transfused. If not returned, problems may be caused later if, subsequently, a recall notification is received concerning the safety of the "transfused" product. Residual components intentionally not transfused, as with cases of pediatric patients getting a lower volume than the entire unit, need not be returned to the Blood Bank.

11. Transfusion of Blood and Blood Products.

a. Equipment and Supplies. Establish venous access (generally 18- or 20-gauge angiocath for adults; 22 or 24 gauge for pediatrics), central or peripheral; normal saline (0.9%), which may be part of the blood administration set; special filters as indicated, according to specific blood product ordered; and Y-type connector, if necessary. Obtain blood product to be transfused only after access is accomplished. The SF518 is attached to the blood product when issued by the Blood Transfusion Service.

b. Patient Identification. Clerical errors cause most acute and fatal transfusion reactions, therefore patient and product verification is the single most important function prior to the administration of blood products. A registered nurse transfusing blood products must first verify the original physician's order. Immediately prior to beginning a transfusion, the patient's wrist identification band must be examined and compared to the identification shown on the SF 518 attached to the unit of blood. Under no circumstances will blood be transfused to a patient who does not have an identification wristband. Check for a "same last name alert" if appropriate. If the name, family member prefix, and social security number of the SF 518 are not identical to that on the patient's wristband, the transfusion must not be started and the Blood Bank must be notified immediately. Two individuals, one of whom is either a registered nurse or physician must verify the identification of the patient, the donor unit number, as well as donor and recipient ABO and Rh types, and document this procedure by signing the relevant blocks in Section III of the SF 518. Neither the SF 518 copy marked "Transfusion Service Copy" nor the unit number on the face label are to be removed from the unit. They provide the positive patient/unit identification necessary for a complete clerical check in the event of a transfusion reaction. Additional unit number labels may be available on the back of product containers for placement in the patient's chart, to avoid transcription errors; otherwise the number must be transcribed into the chart.

c. Patient Education. Physicians will discuss aspects of blood transfusion when obtaining consent. The transfusionist will discuss transfusions with patients prior to blood administration. Inform the patient of the procedure, blood product to be given, approximate time the infusion will take, and reason for transfusion. Instruct the patient to report to the nursing staff any signs of an adverse reaction, such as flushing, chills, headache, nausea, and/or difficulty breathing.

d. Premedication. Patients may be pre-medicated to reduce the potential of minor allergic reactions and/or discomfort, in accordance with the prescribing physician's orders. Pre-medication should not be given more than 30 minutes before the transfusion. Never add medications directly to blood products.

e. Infusion Set. All blood and blood products will be administered through a standard blood infusion set. Ensure correct tubing is selected. The ALARIS type blood administration sets are Y-type tubing sets containing a filter. The package for the ALARIS blood administration set is labeled "Blood Set" and is approximately twice the size of the non-blood transfusion IV set package. The routine blood product filter pore size is approximately 170-260 microns. Micropore (20 to 40 micron) filters may occasionally be useful for whole blood or red cell products, but such micropore filters must never be used for the infusion of granulocyte concentrates. Some micropore filters are also not suitable for platelet concentrates and therefore manufacturers' directions or the Blood Bank must be consulted before infusing platelet concentrates through them. When there are clear indications for the use of leukodepleting filters (e.g., repeated febrile reactions, bone marrow transplant recipients, CMV negative products are not available for a patient requiring them, etc.) an appropriate filter will be used.

f. Leukocyte reduction filters (Leukopore) are available for ward issue from the Materiel Distribution Branch. When used, an additional standard blood infusion filter is not required. Consult the manufacturer's instructions for use. Products that are labeled as Leukocytes, Reduced need only standard bedside filtration; use of an additional white cell filter may reduce the effectiveness of the transfusion. If there is a question regarding filters, the Blood Bank Medical Director should be consulted.

g. Blood products must not be mixed with or infused through the same tubing as any intravenous solutions or medications with the exception that packed red blood cells may be mixed with 0.9% sodium chloride injection, USP to facilitate administration. In specific instances (apheresis), blood may be infused with compatible plasma or with 4-5% albumin in normal saline. Lactated Ringers, water, and other solutions and medications have not been approved and MUST NOT be infused in the same tubing as, or mixed with, blood products. Potentially dangerous clotting or hemolysis may occur.

h. For infusion of whole blood or packed cells, an 18- or 20-gauge angiocath is recommended. A thin-walled, 22-gauge "scalp vein" needle is useful for pediatric patients, or adults with small veins. Decreased needle size reduces the flow of red cells significantly and increases the chance for hemolysis. Other products are usually unaffected by angiocath. When multiple units of blood or blood products are given simultaneously, the units must be given through separate IV lines and must never be mixed together or infused through a common Y-set.

i. Intravenous (IV) Site Preparation. Prepare the transfusion site according to hospital protocol. Select a large vein in a location that will allow the patient some degree of mobility. Place the Y-type extension set at the hub of the intravenous

catheter. The Y-type extension set will allow for immediate access if there is an adverse reaction. Start the intravenous infusion with normal saline (0.9%) only- other IV solutions may cause red cell hemolysis. Once venous access has been established, complete the WRAMC Form 1321 and obtain the blood product from the Blood Bank. Inspect the blood product for abnormal color, cloudiness, clots or excess air. Platelets are normally cloudy, plasma should be clear.

j. Blood Warmers. Occasionally patients may require blood or other IV fluids to be warmed prior to infusion. Equipment for warming blood safely is available from the Blood Bank, for ward use. Equipment may be signed out for use with specific patients. Anesthesia maintains blood warmers for use in the Operating Rooms. For ward patients, warming blood is generally not needed. Such equipment is recommended if blood is to be given rapidly (e.g., 100 mL/minute, 10 units over 30 minutes). If needed, call the Blood Bank and obtain a blood warmer. Excessive warming of blood may cause red cell hemolysis. Patients with history of cold agglutinins may also benefit from a blood warmer. Blood should only be warmed with devices designed for this purpose.

k. Completion of SF 518. Prior to beginning the transfusion, the "Pre-Transfusion Data" portion of "Section III - Record of Transfusion" must be completed by the individual RN or physician starting the transfusion. Pre-transfusion vital signs (temperature, pulse, and blood pressure) must be taken just before the transfusion and recorded on the SF 518. Establishing baseline vital signs allows for the detection of changes that may indicate an adverse reaction. If the patient's temperature is greater than 101F, notify a physician prior to administering blood on a ward. Immediately prior to the transfusion; confirm that the donor number, blood type and Rh factor on the bag match those on the SF 518. Verify the patient's hospital ID band with the patient identification on the SF 518 attached to the blood bag to ensure the correct patient receives the intended blood product. Upon completion of the transfusion, the appropriate portion of SF 518 Section III "Post Transfusion Data" must be completed, and the Medical Record Copy placed in the patient's chart. When available, automated data collection may replace this manual system.

l. Starting the Transfusion- Rate and Duration of Infusion. Only a registered nurse (RN) or physician should start the blood transfusion. During the first twenty minutes, the infusion should be administered slowly (2-3 mL/minute), with close observation of the patient. This monitoring of the patient should be done by an RN or physician. Patient's vital signs, including temperature, will be rechecked every fifteen (15) minutes for the first 60 minutes. Signs of a severe transfusion reaction usually occur during the infusion of the initial 50-100 mL. If no adverse reaction is observed in the first 20 minutes, the blood or blood product may be administered at the rate prescribed, which should be as quickly as possible without provoking problems with fluid overload. The

Date of Transfusion and Time Started, as well as Time/Date Completed/Interrupted are recorded, as appropriate, in Section III of the SF 518. The transfusion should be completed within four hours of blood product issue from the Transfusion Service.

m. If a transfusion is not completed within four hours, contact the Blood Bank before discontinuing the blood. Avoid the use of pressure bags to increase blood transfusion rates for red cells. Research has shown that uneven distribution of pressure over the bag can lead to red cell lysis. If pressure bag use is unavoidable, do not apply more than 200mm Hg of pressure. The use of infusion pumps should be reserved for situations where the patient's condition warrants judicious monitoring of the blood infusion.

n. Nursing (Transfusionist) Responsibilities. Blood must be hung by registered nurses (RNs) only. Patient education, safety, and the monitoring of the blood administrations are nursing responsibilities. Stopping the transfusion at the time of a suspected reaction is the transfusionist's responsibility. Notify the physician and the Blood Bank immediately of any suspected adverse reaction. Record in CIS or outpatient record, as appropriate (Progress Notes – Nursing; vital signs flow chart) and on the SF518, the time the blood was hung, gauze, needle and blood transfusion product numbers located on the container/ blood bag, as well as the patient's vital signs and how the patient tolerated the procedure. Transfusion documentation is essential in assisting the investigation of any delayed reaction such as hepatitis or Human Immunodeficiency Virus (HIV).

o. Physician Responsibilities. Patient informed consent and safety in the administration of blood products, completion of the SF 518, and evaluation and treatment of possible transfusion reactions are responsibilities of the patient's physician. The physician orders the transfusion, documents consent, the clinical plan and occurrence of the transfusion, including the clinical justification for, and response to the transfusion, as well as evaluation of any adverse effect and treatment.

p. Intra-Operative Records. The transfusion of each unit of blood administered to a patient under anesthesia will be recorded by the unique blood unit number on SF 517 (Clinical Record - Anesthesia), along with start and stop times and the volume infused, so that the total amount administered is known at all times and, in the event of an adverse reaction, units of blood under suspicion can be accurately identified.

q. Clinical Records. The SF 518 will be included in the Medical Record. This documents the unique blood donor number, the time of administration, who administered/ identified patient and blood product, and the patient's condition before, during and at the end of transfusion. Indications and response data will be recorded in

the medical record (CIS) by the physician. Nursing notes will also include this information and will provide supplemental information and documentation of actions.

r. Exceptions to SF 518 Completion. Certain products (WinRho, RhoGam) do not require vital signs or administration times.

12. Release, Return, and Suitability for Further Use.

a. Unless specific arrangements are made with the Blood Bank Pathologist-on-Call, units crossmatched for a particular patient will be automatically released into the general inventory between 0030 hours and 0700 hours, two (2) calendar days after the patient sample was received. Crossmatches for Operating Room cases will be released at 2400 hours the day of surgery, if the patient has not used a significant amount of blood.

b. Never store blood products on the ward. When blood products have been issued from the Blood Bank and are returned unused, they will be quarantined. If they have been out of the Blood Bank 30 minutes or longer, they will be discarded. Units not maintained under documented storage conditions throughout their shelf life will not be reissued without the approval of the pathologist covering the Blood Bank. Blood should not be picked up from the Blood Bank until just prior to the intended transfusion. If a delay of more than 30 minutes in starting the transfusion is anticipated, the blood should be immediately returned to the Blood Bank. Product waste is currently monitored by the Blood Usage Committee.

13. Transfusion Reactions.

a. The AABB standard 7.3 states: "An adverse event experienced by a patient in association with a transfusion shall be regarded as a suspected transfusion complication." If a suspected adverse reaction to transfusion of blood or blood products occurs, immediately stop the infusion; allow the blood product to remain hanging and keep the vein open by infusing Normal Saline. Immediately notify the patient's physician and the Blood Bank. Do not discard IV tubing or blood product. The pathologist covering the Blood Bank will be notified and will consult with the patient's physician to determine the nature and severity of the problem and the diagnostic tests that will be performed to evaluate the reaction. Reactions consisting only of urticaria may, at the discretion of the physician, be treated and the transfusion cautiously resumed. Walter Reed Army Medical Center (WRAMC) Department of Pathology and Area Laboratory Services (DPALS) Form 186 (Transfusion Reaction Worksheet) will be completed by the Blood Bank Staff and the pathologist.

b. **Recognition of a suspected transfusion reaction.** Evidence of a transfusion reaction may include one or more of the following symptoms: heat at the site of infusion, flushing, itching, rash, hives, wheezing, fever $\geq 1^{\circ}C$ ($\geq 2^{o}F$) rise from baseline, chills, back pain, feeling of head-fullness, headaches, chest pain, nausea, vomiting, drop in blood pressure, unexplained increase in pulse, oliguria, anuria, shock, muscle pain, diffuse bleeding, and diarrhea.

c. **Action to take.** Time is of the essence in the evaluation of suspected hemolytic transfusion reactions. No clinical sign or symptom is reliable in making this diagnosis with accuracy. Therefore, immediate action to lessen the severity of injury is important. In the event the patient has a reaction, the following steps will be taken (also in 13a. above):

(1) Discontinue the transfusion immediately, in a manner that protects the sterility of the unit.

(2) Maintain an IV route by keeping the vein open with normal saline.

(3) Notify the physician and the blood bank of the reaction.

(4) Obtain vital signs, assess the patient, and provide supportive care and treatment as required.

(5) Perform bedside check of patient and unit identifiction.

(6) Submit the following to the blood bank (NOTE- if the reaction is urticarial only, or is clearly due to fluid overload, the treating physician may elect to waive the following work-up. Such reactions should still be reported to the blood bank and consulted with the blood bank physician):

(a) One 5 mL lavender top tube.

(b) The blood product container and infusion set of the suspected unit (transport in red plastic biohazard bag), including the attached patient ID form (3rd copy of the SF 518). Tie a knot in the tubing tight enough for the tubing to turn white/opaque, so that the liquid will not leak or become contaminated (Exception: when infusion is restarted after treatment of an urticarial reaction).

(c) The second copy of the <u>completed</u> SF 518 for the suspected unit, indicating interruption time, volume infused and suspicion of a reaction.

(d) If hemolysis is suspected, the first voided urine should be sent to the lab for urinalysis.

d. Walter Reed Army Medical Center (WRAMC) Department of Pathology and Area Laboratory Services (DPALS) Form 186 will be initiated by the Blood Bank. Clinical or nursing staff will be asked to provide the following information: suspected blood unit number; time and date of reaction; nature of reaction (to include changes in temperature, flank pain, burning at site of infusion, chills or shortness of breath); physical findings such as jaundice, bleeding diathesis, edema; and relevant lab data such as elevated liver function tests, hemoglobinuria, hemoglobinemia.

e. The ward and/or patient's physician will be notified of the results of all tests immediately upon completion. The information on the completed WRAMC DPALS Form 186 will be entered into the patient's CHCS file (Transfusion Reaction Report test) as soon as possible, usually within 48 hours. NOTE: if the reaction is circulatory overload or if hives are the only manifestation, blood samples and the unit need not be collected or brought to the Transfusion Service.

f. The following **types of suspected transfusion reactions** must be reported to the Blood Bank:

(1) Acute Hemolytic Reaction: This has been reported to be the most common cause of death due to transfusion, usually because of clerical error in identifying the patient, blood tube sample, or blood unit. It usually occurs in cases where a patient receives blood of the wrong blood type and develops intravascular hemolysis. These reactions can be fatal and prompt medical care is essential. Signs and symptoms may include fever, the feeling of heat along the vein in which the blood is being transfused, pain in the lumbar region, chest pain, tachycardia, hypotension, and hemoglobinemia with subsequent hemoglobinuria and hyperbilirubinemia. Serious sequelae include shock, disseminated intravascular coagulation, and renal failure. Uncontrollable bleeding due to disseminated intravascular coagulation may be the only sign of a hemolytic transfusion reaction in an unconscious patient. Such a reaction may not be accompanied by hypotension.

(2) Delayed Hemolytic Reactions: These reactions can be serious, though usually innocuous, and due to the transfusion of incompatible blood. In this type of reaction, the antibody titer is usually undetectable by routine screening procedures and rises slowly in two to 14 days. As it rises, incompatible transfused blood cells are removed in the spleen in the extravascular spaces. Although the hematocrit may drop and jaundice may be seen, generally there are no life-threatening complications. Subsequent transfusions must be with blood negative for the antigen that provoked the reaction.

(3) Anaphylactic Reactions: These reactions are generally due to prior patient sensitization to plasma proteins, most commonly IgA, and can be life-threatening. The patient must be managed for anaphylactic shock. The most severe form of allergic reaction, anaphylactic reaction signs and symptoms generally affect a tetrad of general categories: cutaneous, respiratory, cardiovascular and gastrointestinal. Reactions can include uticaria, flushing, upper airway obstruction (stridor, wheezing, dyspnea), shock, tachycardia, nausea, vomiting, abdominal cramps, and diarrhea. Severe reactions generally occur within seconds to minutes after the start of a transfusion.

(4) Septic Reactions: These are due to bacterial contamination of products, can be life-threatening, and require prompt medical attention. The immediate reaction is due to preformed bacterial toxins that have accumulated in the blood product. Sepsis, subsequent to transfusion, occurs if the bacterial load is great and the patient's immune system is unable to cope with it. Manifested by rapid onset of chills, rigors, high fever, vomiting, diarrhea, and/or marked increase or decrease in blood pressure or pulse, the reaction can be confused with hemolytic reactions, anaphylactic reactions, and transfusion-associated acute lung injury (TRALI). The Blood Bank or the physician may request cultures of the patient’s blood. Treatment consists of antibiotics, IV fluids, vasopressors, and/or steroids, as prescribed. Bacterial contamination is more common in platelet blood components than in red cells and plasma, and reactions during and after platelet transfusion should raise suspicion for this type of reaction.

(5) Allergic Reactions: These reactions manifest the following symptoms: flushing, itching, rash, uticaria, hives, asthmatic wheezing, laryngeal edema, and/or anaphylaxis. Administer antihistamine as directed, observe for anaphylaxis: prepare epinephrine if respiratory distress is severe. If hives are the only clinical manifestation, the transfusion may be continued at a slower rate with close monitoring for recurrence and the potential onset of more severe signs or symptoms. The decision to restart a transfusion in a patient with a uticarial reaction is made by the patient’s physician; the transfusion is restarted after treatment for the uticaria, and is discontinued if the reaction progresses. Uticarial reaction is the ONLY reaction for which restarting is routinely acceptable.

(6) Febrile (Non-Hemolytic) Reactions: These are the most common of the transfusion reactions and are not life-threatening. Febrile (non-hemolytic) reactions are usually due to the patient's immune response to HLA or other non-red cell antigens present in the transfused blood components. These types of reactions can usually be treated with anti-pyretics after a full investigation; they are manifested by sudden chills and fever, headache, flushing, and/or anxiety. Check the patient’s temperature 30 minutes after chill, and as indicated thereafter. Give antipyretics as prescribed and treat symptomatically. The distinction between fever due to transfusion and fever related to the underlying disease can be impractical to make. Because of the

seriousness of transfusion reactions, fever rising during transfusion is best regarded as a suspected transfusion reaction. This type of reaction can also occur in the few hours after a transfusion, and the differential diagnosis includes the life-threatening hemolytic and septic reactions.

(7) Transfusion Related Acute Lung Injury (TRALI): Transfusion Related Acute Lung Injury is a well-characterized clinical constellation of symptoms including dyspnea, hypotension, and fever. The radiological picture is that of bilateral pulmonary infiltrates without evidence of cardiac compromise or fluid overload. Symptoms typically begin 1-2 hours after transfusion and fully manifest within 1-6 hours. Transfusion recipients who develop TRALI may have had a predisposing event such as surgery, active infection, massive transfusion or cytokine therapy, that causes activation of the pulmonary endothelium and priming of the recipient's white blood cells. Respiratory support should be as intensive as dictated by the clinical picture.

(8) Graft vs. Host Disease. This uncommon but often fatal reaction usually occurs in immune incompetent recipients, or recipients of blood from blood relatives. Manifestations include fever, diarrhea, abnormal liver associated tests, and skin rash. Onset is usually 8-10 days following transfusion. Transfused T cells from the blood component react to recipient tissues and cause the injury. This reaction is prevented by irradiation of cellular blood components for patients at risk.

(9) Circulatory Overload: This type of reaction is manifested by a rise in venous pressure, distended neck vein(s), dyspnea, cough, crackles at base of lungs. Notify the physician and the Blood Bank. Place the patient in semi-Fowler's position and administer treatment as prescribed (e.g. diuretics, oxygen, morphine, or aminophylline).

g. Fatal Reactions. Any fatality that may have been associated with the donation or transfusion of blood products must be immediately reported to the Blood Bank Medical Director or Staff Pathologist-on-Call. Within 24 hours, the Blood Bank staff must notify the Food and Drug Administration of any confirmed fatalities through the Army Blood Program Office, Headquarters, United States Army Medical Command, 2050 Worth Road Suite 10, Fort Sam Houston, TX 78234-6010, telephone (210) 221-6344, FAX (210) 221-6614 (21 Code of Federal Regulations 606.170[b]); a written report must follow within no more than seven (7) days. The Food and Drug Administration Center for Biologics Evaluation and Research (CBER) telephone number is (301) 827-6220, FAX (301) 827-6748, e-mail fatalities2@cber.fda.gov. A complete evaluation will be performed and the report forwarded to the WRAMC Blood Usage Committee, and to Risk Management for forwarding to JCAHO as a Sentinel Event.

h. Risk Management Incident and Sentinel Event: If any provider (nurse, physician,

laboratory technologist, etc.) identifies a variation from policy that may have contributed to a transfusion reaction, he/she should report it to the Risk Management Office using WRAMC Form 1811 (Risk Management/ Quality Improvement Report). If anyone identifies a hemolytic transfusion reaction involving administration of blood or blood products, patients with major blood group incompatibilities or a case of blood administered to a non-intended recipient, he/she should also submit a WRAMC Form 1811.

14. Infectious Complications: These occur when transfusion- transmissible infectious agents are present in blood components that are subsequently transfused. Because all blood components are tested for Hepatitis B, Hepatitis C, HIV, Human T-lymphotrophic virus and syphilis, these post-transfusion complications are rare. Nevertheless, all patients diagnosed with the above infections, who may have been transfused with blood products within the previous 12 months, must be reported to the Medical Director of the Blood Bank.

a. Post-Transfusion Hepatitis.

(1) In accordance with FDA regulations and AABB standards, the Blood Bank Medical Director will evaluate all suspected cases of post-transfusion hepatitis at WRAMC. The transfusion history of confirmed cases will be thoroughly investigated, in an attempt to identify the donor(s) most likely involved in transmitting the illness. Such donor(s) may be disqualified from future donations.

(2) Suspected cases are defined as any patients with acute or chronic hepatic dysfunction who has been transfused during the preceding two (2) weeks to six (6) months, or whose transfusion history is unknown or uncertain.

(3) The Preventive Medicine Service is responsible for directly reporting suspected cases to the Blood Bank.

(4) The individuals listed in paragraph (5) below will establish a reliable system within their departments to ensure the recognition and reporting of all suspected cases of post-transfusion hepatitis. These individuals will submit a memorandum no later than the last working day of each month to the Medical Director of the Blood Bank, providing the following information on every suspected case detected:

(a) Patient's first and last names.

(b) Patient's family member prefix.

(c) Sponsor's social security number.

(d) Dates of transfusion (if known).

(e) Basis for diagnosis of liver dysfunction (i.e., elevated ALT, biopsy, etc.)

(5) Reporting centers:

(a) Chief, Infection Control Nursing Service.

(b) Chief, Department of Medicine.

(c) Chief, Gastroenterology Service.

(d) Chief, Infectious Disease Service.

(e) Chief, Department of Surgery.

(f) Chief, Department of Pediatrics.

(g) Chief, Department of Obstetrics & Gynecology.

(h) Director, Patient Administration.

(i) Chief, Department of Primary Care and Community Medicine.

(j) Chief, Anatomic Pathology Service.

(6) Following complete evaluation of all reported cases, the Medical Director will take appropriate actions to prevent future donations by any individual deemed responsible for transmission of a case of post-transfusion hepatitis.

b. Post-Transfusion Infection with the Human Immunodeficiency Virus (HIV).

(1) Suspected transfusion-associated HIV and/or AIDS will be evaluated by the Medical Director, Blood Bank. The transfusion history of confirmed cases will be investigated to attempt to identify donor(s) most probably involved in transmitting the illness. Such donors are disqualified from future donations.

(2) Suspected cases are defined as patients who either meet the Centers for

Disease Control and Prevention criteria for Acquired Immune Deficiency Syndrome (AIDS), have a clinical diagnosis of AIDS-related complex, or test positive for antibodies to the HIV and who also have a history of prior transfusion. Transfusion includes treatment with any human blood or plasma derived products.

(3) All staff at WRAMC are responsible for directly reporting suspected cases to the Blood Bank. Moreover, the Medical Director will maintain a liaison with the Preventive Medicine Service to ensure a reliable system exists to recognize and report suspected cases.

(4) The following information for each suspected case of transfusion associated Acquired Immunodeficiency Syndrome (AIDS) will be reported to the Blood Bank Medical Director:

(a) Patient's first and last names.

(b) Patient's identification number (family member prefix - sponsor's social security number).

(c) Clinical history.

(d) Dates and locations of transfusions.

(5) Following evaluation of suspected transfusion- related AIDS, the Blood Bank Medical Director will take actions to initiate the appropriate evaluation of implicated donors. If blood was obtained through the WRAMC Blood Donor Center, notification and evaluation will be coordinated with Infectious Disease Service and Preventive Medicine Activity. Where blood was obtained from other sources, suppliers will be notified of implicated units.

15. Blood Donor and Transfusion Recipient Program. Department of Defense (DoD) policy requires any military health care beneficiary (HCB) identified as HIV-infected be questioned by individuals designated by the Medical Advisory (Look Back) Committee, about blood transfusions received from and donations made to either a military or civilian blood program since the beginning of calendar year 1977. The results of the interview will be provided to the WRAMC Medical Advisory Committee, who in turn will ensure the information is forwarded to appropriate authorities for follow-up. In addition, when a current blood donor is identified as HIV-infected, the Blood Bank Medical Director will initiate a search of blood bank records and provide information concerning recipients and other disposition of blood or blood products to the Look Back Committee for follow-up.

16. Blood Usage Review.

a. Screening criteria for the audit of blood component usage are established and approved by the Blood Usage Committee. Walter Reed Army Medical Center (WRAMC) Forms 1321 are screened by the staff of the Transfusion Service; those that do not appear to meet transfusion criteria will be forwarded to the Blood Bank Medical Director for review. If a transfusion does not meet the established practice patterns as determined by the Blood Bank Medical Director, the case will be referred to the chief of the ordering service or the designated Blood Usage Committee member. The service chief or committee member will then review the case and return appropriate comments to the full committee at the next meeting.

b. Blood Usage Committee Membership includes representatives of the following:

(1) Laboratory Services (Chief, DPALS)

(2) Medicine

(3) Anesthesia & Operating Services

(4) Pediatrics

(5) Nursing

(6) Obstetrics/Gynecology

(7) Surgery

(8) Orthopedics and Rehabilitation

(9) Blood Services:

(a) Medical Director

(b) Chief, Blood Services

The proponent agencies for this publication are the Department of Pathology and Area Laboratory Services, the Blood Usage Committee, and Nursing Services. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, Walter Reed Army Medical Center, ATTN: MCHL-U, 6900 Georgia Avenue NW, Washington, DC 20307-5001.

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